

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

JAMES TONRA, Ph.D.,

Plaintiff,

18-cv-9028 (JGK)

- against -

OPINION AND ORDER

KADMON HOLDINGS, INC. ET AL.,

Defendant.

JOHN G. KOELTL, District Judge:

The plaintiff, James Tonra, Ph.D., brings this action against the defendants, Kadmon Holdings, Inc. ("Kadmon" or "the company"), Harlan W. Waksal, M.D. ("Waksal"), and John Ryan, M.D., Ph.D. ("Ryan") (collectively, "the defendants"). The plaintiff alleges that, by repeatedly failing to pay the plaintiff his annual bonus, the defendants committed breach of contract, breach of the implied covenant of good faith and fair dealing, and breach of New York Labor Law ("NYLL") § 193. The plaintiff also alleges that the defendants violated the whistleblower provisions of the NYLL, §§ 215 and 740, and the Sarbanes-Oxley Act ("SOX") § 806, 18 U.S.C. § 1514A, by firing the plaintiff after the plaintiff expressed concerns that the company would not report negative test results for the company's drug candidate, tesevatinib. The defendants move to dismiss the plaintiff's Amended Complaint under Federal Rule of Civil Procedure 12(b)(6) for failure to state a claim upon which

relief can be granted. For the reasons explained below, the defendants' motion to dismiss is **granted in part and denied in part.**

I.

In deciding a motion to dismiss pursuant to Rule 12(b)(6), the allegations in the complaint are accepted as true, and all reasonable inferences must be drawn in the plaintiff's favor. McCarthy v. Dun & Bradstreet Corp., 482 F.3d 184, 191 (2d Cir. 2007). The Court's function on a motion to dismiss is "not to weigh the evidence that might be presented at a trial but merely to determine whether the complaint itself is legally sufficient." Goldman v. Belden, 754 F.2d 1059, 1067 (2d Cir. 1985). The Court should not dismiss the complaint if the plaintiff has stated "enough facts to state a claim to relief that is plausible on its face." Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570 (2007). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009).

While the Court should construe the factual allegations in the light most favorable to the plaintiff, "the tenet that a court must accept as true all of the allegations contained in the complaint is inapplicable to legal conclusions." Id. When

presented with a motion to dismiss pursuant to Rule 12(b)(6), the Court may consider documents that are referenced in the complaint, documents that the plaintiff relied on in bringing suit and that are either in the plaintiff's possession or that the plaintiff knew of when bringing suit, or matters of which judicial notice may be taken. See Chambers v. Time Warner, Inc., 282 F.3d 147, 153 (2d Cir. 2002).

II.

The following allegations are taken from the Amended Complaint and are accepted as true for purposes of this motion.

A.

In July 2011, the plaintiff began negotiating with the defendants about joining Kadmon as an employee. Am. Compl. ¶ 25. On July 25, 2011, after several weeks of negotiating the terms and conditions of the plaintiff's employment, Kadmon sent the plaintiff a final employment agreement. Id. ¶ 26. The agreement contained a bonus provision, which read:

[The plaintiff] will receive a guaranteed bonus equal to one third of [his] annual base salary. For calendar year 2011, this bonus will be subject to [the plaintiff's] performance. Subsequent to 2011, the bonus may be adjusted based on [the plaintiff's] performance as well as Company performance. Annual bonuses will be paid no later than March 15th following the year in which they are accrued.

Kennedy Decl. Ex. A. (emphasis added). Around August 2011, the plaintiff signed the employment agreement and became Kadmon's Vice President of Preclinical Pharmacology. Am. Compl. ¶ 30. The plaintiff's responsibilities included advancing projects from the research stage of development to the clinical trial stage of development and "assuming primary responsibilities for enrollment, data analysis and interpretation and scientific interactions with investigators." Id. ¶¶ 32-33.

While employed at Kadmon, the plaintiff received only two bonuses, one in 2012 and one in 2013. Id. ¶ 43. However, the plaintiff alleges that he was contractually entitled to bonuses for every year he worked between 2011 and 2016. Id. ¶¶ 41-42. Of the two bonuses that the plaintiff received, the plaintiff alleges that only one was sufficient under his employment agreement. In 2012, Kadmon paid the plaintiff a \$127,500 bonus, which exceeded the alleged contractually guaranteed amount of one-third the plaintiff's base salary. Id. ¶¶ 29, 44; Kennedy Decl. Ex. A. The 2013 bonus, however, amounted to less than one-third the plaintiff's base salary. Am. Compl. ¶ 44.

On January 11, 2017, the plaintiff contacted employees in Kadmon's legal department about the company's failure to pay his bonuses. Id. ¶¶ 116-17. The plaintiff told the legal department that he had not received his bonus for several years and that his 2013 bonus was less than the amount that he

believed he was contractually guaranteed to receive. Id. ¶¶ 117-18. Despite following up on his complaint around February 2017, the company never paid the plaintiff's requested bonuses. Id. ¶¶ 120-21.

In 2017, the plaintiff met with one of his supervisors, defendant Waksal, to discuss the plaintiff's compensation. Id. ¶¶ 58-59. During this conversation, Waksal offered the plaintiff \$75,000 and 10,000 stock options, with the promise of more stock options in the future, if the plaintiff agreed to renegotiate his employment agreement with Kadmon. Id. ¶ 59. The plaintiff did not receive the stock options for another eight months, and, as of September 2017, he had not received the \$75,000. Id. ¶ 61. Also as of September 2017, the plaintiff had not received a formal response from Kadmon regarding whether the company had investigated any of the plaintiff's concerns about his compensation. Id.

Around September 11, 2017, the plaintiff filed another complaint with Kadmon's legal department, asking the company to pay him his unpaid bonuses. Id. ¶¶ 62, 122. Kadmon told the plaintiff that the company would address the issue, but he never received any additional bonus compensation. Id. ¶ 63. On September 28, 2017, after the plaintiff lodged yet another complaint about his bonuses, Kadmon terminated his employment. Id. ¶ 124.

B.

Around August, 2016, before the plaintiff's employment was terminated, Kadmon was researching novel glucose transport inhibitors and Rho-associated kinase inhibitors in connection with the development of a number of new drugs. Id. ¶ 65. During meetings about this research, the plaintiff criticized the company's strategy regarding the development of these drugs because they allegedly posed serious risks of male fertility toxicities and hypotension. Id. ¶¶ 67, 69. Because of these risks, the plaintiff recommended that Kadmon stop developing these drug candidates. Id. ¶ 70. Not only did Kadmon ignore the plaintiff's suggestions, but Kadmon also excluded the plaintiff from further research project meetings. Id. ¶ 71.

Around the end of 2016 and the beginning of 2017, the plaintiff spoke with Masha Poyurovsky, Kadmon's Vice President of Molecular Signaling, about his exclusion from research-team meetings. Id. ¶ 72. Poyurovsky told the plaintiff that he had been excluded because the plaintiff "[kept] raising the same issues and it [was] upsetting the team." Id. ¶ 73. After the plaintiff continued to raise concerns about the Rho-associated kinase inhibitor and the glucose transporter research projects, Kadmon reassigned the plaintiff to a lower-level group within a new research and development department. Id. ¶ 74.

C.

Around July 2017, the plaintiff presented Kadmon's upper management, including the individual defendants, with preliminary findings from an animal study testing tesevatinib, a drug that was being developed by Kadmon for its potential to treat autosomal recessive polycystic kidney disease. Id. ¶¶ 82-83. The preliminary tesevatinib study results were not promising and did not match results from a key study previously conducted by a scientist not affiliated with Kadmon; the preliminary study results showed a correlation between the use of tesevatinib and increased toxicity levels in the kidney and liver. Id. ¶¶ 86-87, 95. The preliminary results also showed no beneficial effects of tesevatinib. Id. ¶ 87. In addition to the drug candidate's lack of efficacy, the preliminary results showed that tesevatinib seemed to be causing other bodily effects that were indicative of organ toxicity for the kidneys and liver. Id. ¶ 88. The plaintiff reported these preliminary results to Waksal and to the plaintiff's direct supervisor, Dr. Cohen. Id.

Within days of the plaintiff's informing upper management of the preliminary findings, defendant Ryan -- a senior executive at Kadmon -- demanded that the plaintiff tell him who ordered the tesevatinib study. Id. ¶ 89. The plaintiff brought another employee into the conversation, and they both confirmed

to Ryan that Ryan had been present at the meetings where the study had been approved. Id. ¶ 90. Ryan told the plaintiff a story about an employee whose employment was terminated for conducting a study that produced negative results. Id. ¶¶ 91-92. The employee in Ryan's story was fired shortly after the study results were announced. Id. ¶ 92. The plaintiff understood from Ryan's story that (1) Kadmon would not communicate the initial tesevatinib study results outside of the company and (2) the plaintiff might be fired if he took any steps that would put Kadmon in a position that would require Kadmon to report the results. Id.

Around September 26, 2017, the plaintiff received the final results from the tesevatinib study, which reported an increased risk of liver and kidney damage. Id. ¶¶ 96-97. Around September 27, 2017, the plaintiff spoke to Kadmon's head of Regulatory Compliance about updating the company's Investigator's Brochure ("IB") and Informed Consent Form ("ICF") for tesevatinib because the plaintiff believed that the risks shown in the final test results should be disclosed in the company's annual update to the Federal Drug Administration ("FDA"). Id. ¶ 99. Kadmon's head of Regulatory Compliance informed the plaintiff that there was a meeting scheduled that day to discuss the annual update to the IB. Id. ¶ 100. The plaintiff attended the meeting. Id. ¶ 101.

At the meeting, the plaintiff informed those present that the company was required to report the data on tesevatinib and update its IB within the next few months. Id. ¶¶ 101-02. The plaintiff believed that if the company updated the IB with the tesevatinib study results, the information would reach investors and inform them of the toxicity risks associated with tesevatinib. Id. ¶ 103. The plaintiff allegedly believed that the company would commit fraud if it did not communicate these results to investors. Id. ¶ 102. The plaintiff also allegedly informed those present at the meeting that the company would pose serious safety risks to the public if it did not disclose the study results. Id. ¶ 104.

On September 28, 2017 -- only two days after the meeting -- Kadmon terminated the plaintiff's employment. Id. ¶ 106. The plaintiff believes that the prior update of the IB occurred in January 2017, and an annual update was scheduled to occur in January 2018. Id. ¶¶ 110, 113. The plaintiff also believes that Kadmon failed to report the tesevatinib results to both the FDA and the company's shareholders. Id. ¶¶ 111-12. The plaintiff claims that the delay in publishing the study results and informing investors was tantamount to fraud. Id. ¶ 114.

The plaintiff alleges (1) that the defendants committed breach of contract by failing to pay the plaintiff contractually guaranteed bonuses for work he performed in 2011, 2013, 2014,

2015, and 2016; (2) that the defendants violated NYLL § 193, which prohibits unauthorized deductions of wages by failing to pay the plaintiff contractually guaranteed bonuses for work he performed in the relevant years because his bonuses constitute "wages" as defined by § 193; (3) that the defendants breached the implied covenant of good faith and fair dealing by failing to pay the plaintiff contractually guaranteed bonuses for work he performed in the relevant years; and (4) that the defendants violated NYLL §§ 215 and 740 and SOX § 806 by firing the plaintiff in retaliation for the plaintiff's complaints to the defendants that they were obligated to report tasevatinib study results to the FDA.

The defendants move to dismiss the complaint under Federal Rule of Civil Procedure 12(b)(6). The defendants argue that the plaintiff (1) fails to state a breach of contract claim and a claim for violation of NYLL § 193 because the bonus provision in the employment agreement stipulates that the bonus was not guaranteed but discretionary; (2) fails to state a claim for breach of the implied covenant of good faith and fair dealing because the employment agreement between the company and the plaintiff is an enforceable contract; (3) fails to state a NYLL § 740 claim because the plaintiff has not stated an actual violation of law causing substantial and specific risk to public safety; and (4) fails to state a NYLL § 215 claim because such a

claim is preempted by NYLL § 740; and (5) fails to state a claim for violation of SOX because the plaintiff has not satisfied the elements of the SOX whistleblower provision.

III.

The defendants argue that the plaintiff's claims related to his unpaid bonuses fail as a matter of law because the bonuses were discretionary and not guaranteed under the plaintiff's employment agreement, and the bonus amounts were dependent on performance by the plaintiff and Kadmon.

A.

"To form a valid contract under New York law, there must be an offer, acceptance, consideration, mutual assent and intent to be bound." Register.com, Inc. v. Verio, Inc., 356 F.3d 393, 427 (2d Cir. 2004) (quotation marks omitted). "It is well settled that for a contract to be valid, the agreement between the parties must be definite and explicit so their intention may be ascertained to a reasonable degree of certainty." Foros Advisors LLC v. Digital Globe, Inc., 333 F. Supp. 3d 354, 360 (S.D.N.Y. 2018) (quoting Candid Prods., Inc. v. Int'l Skating Union, 530 F. Supp. 1330, 1333 (S.D.N.Y. 1982)).

"Whether a contract term is ambiguous is a question of law." Curry Rd. Ltd. v. K Mart Corp., 893 F.2d 509, 511 (2d Cir. 1990). However, the Court should construe a contract as a matter of law only if the contract is unambiguous on its face.

See Metro. Life Ins. Co. v. RJR Nabisco Inc., 906 F.2d 884, 889 (2d Cir. 1990). A contract is unambiguous if it has "a definite and precise meaning, unattended by danger of misconception in the purport of the [contract] itself, and concerning which there is no reasonable basis for a difference of opinion." Sayers v. Rochester Tel. Corp. Supplemental Mgmt. Pension Plan, 7 F.3d 1091, 1095 (2d Cir. 1993) (alteration in original) (quotation marks omitted) (quoting Breed v. Ins. Co. of N. Am., 385 N.E.2d 1280, 1282 (N.Y. 1978)). Where the contractual language is subject to more than one reasonable meaning and where extrinsic evidence of the parties' intent exists, the question of the proper interpretation should be submitted to the trier of fact unless the extrinsic evidence is so one-sided that no reasonable jury could find in favor of the non-moving party. See 3Com Corp. v. Banco do Brasil, S.A., 171 F.3d 739, 746-47 (2d Cir. 1999); Consarc Corp. v. Marine Midland Bank, N.A., 996 F.2d 568, 573 (2d Cir. 1993); Abner, Herrman & Brock, Inc. v. Great N. Ins. Co., 308 F. Supp. 2d 331, 336 (S.D.N.Y. 2004); see also Payday Advance Plus, Inc. v. Findwhat.com, Inc., 478 F. Supp. 2d 496, 502 (S.D.N.Y. 2007).

The defendants argue that the contract's language -- specifically, that the plaintiff's bonus "may be adjusted based on [his] performance as well as Company performance," Kennedy

Decl. Ex. A. -- shows that the bonus was discretionary.

Therefore, the defendants argue that they did not breach the contract by failing to pay the plaintiff a bonus for 2011, 2014, 2015, or 2016, and paying a bonus that was less than one-third of the plaintiff's base salary in 2013.¹

Although the defendants argue that the language of the employment agreement is unambiguous, the contract is ambiguous as to whether the bonus was guaranteed or discretionary. The employment agreement's bonus provision is titled "Guaranteed Bonus." Id. Before the discretionary language relied upon by the defendants is stated in the agreement, the provision states that "[the plaintiff] will receive a guaranteed bonus equal to one third of [the plaintiff's] annual base salary." Id. (emphasis added).

The defendants understandably point to the language in the bonus provision that provides that the "bonus may be adjusted based on [the plaintiff's] performance as well as Company performance." However, the plaintiff reasonably argues that this provision should be construed to provide that the bonus could be

¹ In their motion to dismiss, the defendants argue that the plaintiff's breach of contract claim regarding his 2011 bonus is barred by the statute of limitations for breach of contract claims. The plaintiff does not address this argument in his opposition to the motion to dismiss. Therefore, the defendants' motion to dismiss the plaintiff's breach of contract claim as it relates to the 2011 bonus is **granted**.

adjusted upward depending on his performance and the Company's performance, not that the guaranteed bonus could be reduced.

Whether the bonus provision was mandatory or discretionary is a question of fact. Because there is more than one reasonable interpretation of the bonus provision, the contract is ambiguous and the question of the proper interpretation of the contract cannot be decided on a motion to dismiss. Therefore, the defendants' motion to dismiss the breach of contract claim is **denied**.

B.

The plaintiff alleges that the defendants violated NYLL § 193 because failure to pay the plaintiff contractually guaranteed bonuses for work he performed in 2011, 2013, 2014, 2015, or 2016 constitutes an unauthorized deductions of "wages" as defined by the statute.² Section 193, which governs deductions from employee wages, states that "[n]o employer shall make any deduction from the wages of an employee," except in specific circumstances, which largely benefit the employee including deductions for retirement benefits or healthcare. NYLL § 193(1). Under New York law, it is well settled that the definition of wages, as covered by NYLL § 193, does not include incentive-based compensation plans "where an employee receives

² The parties do not discuss whether a claim under NYLL § 193 for the allegedly unpaid 2011 bonus is barred by the statute of limitations. That argument is therefore not a basis for the motion to dismiss.

a guaranteed salary and may also receive supplemental income based upon the dual performance of the employee and the business or as a result of other factors outside of the employee's control.'" Levion v. Societe Generale, 822 F. Supp. 2d 390, 403 (S.D.N.Y. 2011) (quoting Truelove v. Ne. Capital & Advisory Inc., 702 N.Y.S.2d 147, 149 (App. Div. 2000)), aff'd, 503 F. App'x 62 (2d Cir. 2012). Therefore, discretionary bonuses are not wages under NYLL § 193 because they are dependent, at least in part, on factors outside the employee's control. Id. at 404; see also O'Grady v. BlueCrest Capital Mgmt. LLP, 111 F. Supp. 3d 494, 501 (S.D.N.Y. 2015), aff'd, 646 F. App'x 2 (2d Cir. 2016).

In this case, the defendants argue that because the employment agreement states that the plaintiff's bonus "may be adjusted based on [the plaintiff's] performance as well as Company performance," the bonus is based on factors outside the plaintiff's control, and accordingly, the plaintiff's bonus does not qualify as a wage under NYLL § 193.

However, as explained above, the bonus provision is ambiguous. If the plaintiff is correct that his bonuses were guaranteed, they would be considered wages under NYLL § 193 because mandatory bonuses are "not conditioned upon some occurrence or left to the discretion of the employer." See Koss v. Wackenhut Corp., 704 F. Supp. 2d 362, 368 (S.D.N.Y. 2010) (quoting Aledia v. HSH Nordbank AG, No. 08cv4342, 2009

WL 855951, at *2 (S.D.N.Y. Mar. 25, 2009) (citing Truelove, 702 N.Y.S.2d at 149)); Kolchins v. Evolutions Mkts., Inc., 96 N.E.3d 784, 790 (N.Y. 2018) (holding that a non-discretionary bonus could constitute "nonforfeitable 'wages'"). Whether the bonuses were guaranteed and therefore are wages under NYLL § 193 is an issue of fact that cannot be decided on a motion to dismiss. Esmilla v. Cosmopolitan Club, 936 F. Supp. 2d 229, 252 (S.D.N.Y. 2013) (holding that disputes concerning whether a bonus was discretionary create "an issue of triable fact"). Therefore, the defendants' motion to dismiss the plaintiff's NYLL § 193 claim because the plaintiff's bonuses allegedly do not constitute wages is **denied**.

C.

The plaintiff alleges that by failing to award him contractually guaranteed bonuses for work he performed in 2011, 2013, 2014, 2015, or 2016, the defendants violated the implied covenant of good faith and fair dealing. Under New York law, to state a claim for breach of the implied covenant of good faith and fair dealing, "the plaintiff must allege facts which tend to show that the defendant sought to prevent performance of the contract or to withhold its benefits from the plaintiff." Aventine Inv. Mgmt., Inc. v. Canadian Imperial Bank of Commerce, 697 N.Y.S.2d 128, 130 (App. Div. 1999). "The existence of a valid and enforceable written contract governing a particular

subject matter ordinarily precludes recovery in quasi contract for events arising out of the same subject matter." Beth Israel Med. Ctr. v. Horizon Blue Cross & Blue Shield of N.J., Inc., 448 F.3d 573, 587 (2d Cir. 2006) (quoting Clark-Fitzpatrick, Inc. v. Long Island R.R. Co., 516 N.E.2d 190, 193 (N.Y. 1987)).

The parties agree that the plaintiff's bonuses were governed by the plaintiff's employment agreement. The plaintiff was either entitled to receive the bonuses he claims under the terms of his employment agreement, or he was not entitled to those bonuses. Because a written and enforceable agreement governs the plaintiff's claims, the plaintiff cannot also bring a quasi-contract claim based on the same alleged conduct. Accordingly, the defendants' motion to dismiss the plaintiff's quasi-contract claim for a breach of the covenant of good faith and fair dealing is **granted**.

IV.

The plaintiff alleges that the defendants' decision to terminate his employment constituted retaliation for complaints the plaintiff made to the defendants regarding possible safety issues discovered during the tasevatinib study. NYLL § 740(2)(a), the relevant New York State law governing such retaliation claims, provides that:

[a]n employer shall not take any retaliatory personnel action against an employee because such employee . . . discloses, or threatens

to disclose to a supervisor or to a public body an activity, policy or practice of the employer that is in violation of law, rule or regulation which violation creates and presents a substantial and specific danger to the public health or safety, or which constitutes health care fraud.

"[I]n order to recover under a section 740 claim, [the] plaintiff must show that [he] reported or threatened to report the employer's activity, policy or practice, but need not claim that [he] cited any particular law, rule or regulation at [the] time" that the plaintiff made a report. Webb-Weber v. Cmty. Action for Human Servs., Inc., 15 N.E.3d 1172, 1174 (N.Y. 2014) (quotation marks omitted). At the pleadings stage of the case, the complaint "need not specify the actual law, rule or regulation violated. . . ." Id. An employee's reasonable, good faith belief that such a violation has occurred is insufficient to invoke the statute's protection. Khan v. State Univ. of N.Y. Health Science Ctr., 734 N.Y.S.2d 92, 94 (App. Div. 2001); Capobianco v. Am. Stock Exchange, 649 N.Y.S.2d 688, 689 (App. Div. 1996). But the employee's complaint to the company must "identify the particular activities, policies or practices in which the employer allegedly engaged, so that the complaint provides the employer with notice of the alleged complained-of conduct." Webb-Weber, 15 N.E.3d at 1174.

The plaintiff alleges that the defendants violated FDA regulations -- specifically 21 C.F.R. §§ 312.32 and 312.55 -- by

not properly disclosing the results of the tesevatinib study as required by those regulations. The plaintiff alleges that the defendants retaliated against him for bringing attention to the tesevatinib study's negative results by terminating his employment.

The FDA requires a drug company or sponsor like Kadmon to submit an investigational new drug application ("IND") to obtain permission from the FDA to begin clinical trials. 21 C.F.R. § 312.20(a). Once drug testing begins, the sponsor "shall within 60 days of the anniversary date that the IND went into effect, submit a brief report of the progress of the investigation." Id. § 312.33. The report must include, among other things, information about the most frequent and serious adverse experiences by body systems, information on IND safety reports submitted in the past year related to the drug, and information regarding the drug's performance. Id. § 312.33(b)(1)-(2), (5). The FDA requires an amendment to this annual report when the sponsor obtains information about the drug "that is not within the scope of a protocol amendment, IND safety reports, or annual reports." Id. § 312.31(a).

Beyond the annual updates to the IND, the sponsor "must notify FDA and all participating investigators . . . in an IND safety report of potential serious risks . . . in no case later than 15 calendar days after the sponsor determines that the

information qualifies for reporting." Id. § 312.32(c)(1). A sponsor must report (1) a serious and unexpected suspected adverse reaction; (2) results from other studies that suggest a significant risk to humans exposed to the drug; (3) findings from animal or in vitro testing that suggest significant risk in humans exposed to the drug; and (4) increased rate of occurrence of serious suspected adverse reactions. Id. § 312.32(c)(i)-(iv).

Based on the plaintiff's allegations and the related contemporaneous documents, the plaintiff has failed to allege that he had a reasonable good faith belief that Kadmon was violating a law, rule, or regulation that resulted in public endangerment. The plaintiff alleges that the initial tesevatinib trial results in an animal study showed signs of increased toxicity levels in the kidney and liver and that, based on a key model in the study, the drug showed no beneficial effects. Because of these early results, the plaintiff informed Kadmon's upper management that he did not think that Kadmon could replicate a similar, but successful, independent study conducted by Dr. Ellis Avner ("the Avner study").³ The plaintiff alleges that the increased risk of damage to the kidney and

³ Indeed, the final results from Kadmon's study did not replicate the Avner study. The final results from Kadmon's study indicated that the drug created a "potential for increased liver and kidney damage." Am. Compl. ¶ 96.

liver in the company's study warranted reporting to the FDA because it represented a significant risk to the public and that failure to disclose the risks would be tantamount to fraud.

However, the plaintiff's own emails to Kadmon's management about the tesevatinib animal study show that the plaintiff did not have a reasonable belief that failure to disclose the results would pose a risk to the public health sufficient to merit an amendment or safety report.⁴ In an email sent on September 27, 2017, the plaintiff wrote:

[W]e have noted [REDACTED]
[REDACTED]
[REDACTED] so again, you can consider
updating the IB [Investigator's Brochure]
and ICF [Informed Consent Form] with this
new data in the next scheduled update.
[REDACTED]
[REDACTED] thus can wait
for the inclusion in these documents at the
next scheduled update.

. . .

Please note that the final call as to the use of this new nonclinical safety and pharmacodynamics data with regard to clinical/regulatory document updates is of course up to you, so just let me know if I can assist in any way.

⁴ When presented with a motion to dismiss, the Court may consider documents that are referenced in the complaint on which the plaintiff relied in bringing suit. See Chambers, 282 F.3d at 153. In ¶¶ 94 and 100 of the Amended Complaint, the plaintiff relies on two emails, which the defendants have submitted as exhibits B and C to the Kennedy Declaration. Because the plaintiff relied on these emails in the Amended Complaint, the Court may consider the emails in deciding this motion.

Kennedy Decl. Ex. B. (emphasis added). The plaintiff's emails counter his allegation that the company was required to report the tesevatinib study results in order to avoid creating a danger to the public health. Instead of voicing such concern, the plaintiff stated plainly that the results of the study did not need to be disclosed to the FDA until the next scheduled update.

In another internal Kadmon email sent on September 27, 2017, the plaintiff restated his position that the findings from the tesevatinib study created no new safety concerns, and that the tesevatinib results did not need to be disclosed until the next scheduled update. He wrote:

With regard to safety questions, I don't think the study adds any new safety concern that is not already mentioned. Depending on the deadline for the regular IB update, we will incorporate the new data if the final report is ready in time. [REDACTED]
[REDACTED], it is for John or others to decide . . . whether someone outside Kadmon needs to be informed [REDACTED].
[REDACTED].

Kennedy Decl. Ex. C. (emphasis added).⁵

The plaintiff's opining that the information could be incorporated into regularly scheduled updates that were due months after the plaintiff received the results of the study shows that the plaintiff had no reasonable belief that the drug

⁵ While not part of the documents that can be considered on a motion to dismiss, the defendants advised that the FDA was informed of the results of the animal study in March and April, 2018. See Defs.' Mot. Exs. D, E.

posed risks that would require a safety report or amendment of the IND or IB under 21 C.F.R. §§ 312.20(c)(1) or 312.33(a). If the risk to public safety was truly pressing, the plaintiff would not have been content to wait to update the tesevatinib material at the next schedule update point months away from when the plaintiff reviewed the study results. In any event, the plaintiff has not adequately alleged that failure to notify promptly interested parties outside of Kadmon about the drug's alleged inefficacy in an animal study created a substantial danger to public health or constituted health care fraud. The plaintiff's claims thus do not fall under the protection against retaliation that NYLL § 740 provides. See Tomo v. Episcopal Health Servs., Inc., 925 N.Y.S.2d 563, 566 (App. Div. 2011) ("[A]llegations [that] cannot satisfy the element of a threat to public health and safety . . . cannot sustain a cause of action alleging a violation of Labor Law § 740.") (citing cases).

Because the plaintiff has not shown that his complaints to his employer indicated that its failure to report the tesevatinib study results would seriously impact public health and safety, the plaintiff has not stated a claim for whistleblower

retaliation under NYLL § 740. Accordingly, the defendants' motion to dismiss the plaintiff's NYLL § 740 claim is **granted**.⁶

V.

Related to his New York retaliation claims, the plaintiff also alleges that the defendants' decision to terminate his employment due to complaints the plaintiff made regarding the tesevatinib animal study results constitutes a violation of SOX § 806. To bring a successful whistleblower claim under SOX § 806, the plaintiff must plead that he (1) "engaged in protected activity; (2) the employer knew that [he] engaged in the protected activity; (3) [he] suffered an unfavorable personnel action; and (4) the protected activity was a contributing factor in the unfavorable action. If the employee establishe[s] these four elements, the employer may avoid liability if it can prove by clear and convincing evidence that it would have taken the same unfavorable personnel action in the absence of that protected behavior." Bechtel v. Admin. Review Bd., U.S. Dep't

⁶ The defendants argue that the plaintiff's effort to recover under NYLL § 215 should be dismissed because the plaintiff's NYLL § 740 claim preempts his NYLL § 215 claim. Section 740(7) provides that "the institution of an action in accordance with [Section 740] shall be deemed a waiver of the rights and remedies available under any other . . . law, rule or regulation or under the common law." The scope of Section 740(7)'s waiver applies to causes of action related to retaliatory discharge. See Kraus v. Brandstetter, 586 N.Y.S.2d 269, 270 (App. Div. 1992). The plaintiff does not address this argument in his opposition to the motion to dismiss. Therefore, the defendants' motion to dismiss the plaintiff's NYLL § 215 claim is **granted**.

of Labor, 710 F.3d 443, 447 (2d Cir. 2013) (quoting Harp v. Charter Commc'ns, Inc., 558 F.3d 722, 723 (7th Cir. 2009)) (citations and quotation marks omitted). The plaintiff's activity is protected only if he:

provide[s] information . . . regarding any conduct which [he] reasonably believes constitutes a violation of section 1341 [mail fraud], 1343 [wire fraud], 1344 [bank fraud], or 1348 [securities fraud], any rule or regulation of the Securities and Exchange Commission, or any provision of Federal law relating to fraud against shareholders, when the information or assistance is provided to . . . a person with supervisory authority over [the plaintiff]. . . .

18 U.S.C. § 1514A; see also Leshinsky v. Telvent GIT, S.A., 942 F. Supp. 2d 432, 441-42 (S.D.N.Y. 2013).

To demonstrate that he was engaged in protected activity, the plaintiff does not need to prove that the employer actually violated the law. "Rather, he must show that he held a reasonable belief that [the] [d]efendants were engaged in conduct that violated one of the enumerated federal laws" in SOX § 806.⁷ Ashmore v. CGI Grp. Inc., 138 F. Supp. 3d 329, 342 (S.D.N.Y. 2015), aff'd, 923 F.3d 260 (2d Cir. 2019). In other words, the plaintiff must demonstrate that he actually believed that the defendants violated a relevant law and that "a

⁷ To bring a successful SOX claim, the plaintiff need not wait for the violation to occur before filing his complaint. "Imminent crimes, or at least crimes in their infancy" are within the scope of the SOX whistleblower provision. Leshinsky, 942 F. Supp. 2d at 446. Requiring whistleblowers to wait until a violation occurred would frustrate the purpose of the SOX whistleblower provision. Id.

reasonable person in his position would have believed that the conduct constituted a violation." Leshinsky, 942 F. Supp. 2d at 444 (quoting Welch v. Chao, 536 F.3d 269, 278 n.4 (4th Cir. 2008)).

Although the plaintiff is not required to prove that the defendants violated a law or cite a particular provision that he believes the defendants violated, "general inquiries do not constitute protected activity." O'Mahony v. Accenture Ltd., 537 F. Supp. 2d 506, 516 (S.D.N.Y. 2008) (quotation marks omitted) (quoting Fraser v. Fiduciary Trust Co. Int'l, 417 F. Supp. 2d 310, 322 (S.D.N.Y. 2006)). "For the whistleblower to be protected by [SOX], the reported information must have a certain degree of specificity [and] must state particular concerns which, at the very least, reasonably identify a respondent's conduct that the complainant believes to be illegal." Fraser, 417 F. Supp. at 322 (citation omitted). "The statute does not specify what, in particular, a purported whistleblower must establish to demonstrate that criminal fraud or securities-related malfeasance is afoot." Nielsen v. AECOM Tech. Corp., 762 F.3d 214, 221 (2d Cir. 2014). However, courts in this Circuit have construed the statute broadly to protect any employee of a publicly traded company who takes reasonable actions to protect investors or the markets. See Leshinsky, 942 F. Supp. 2d at 440.

The plaintiff alleges that he engaged in a protected activity when he complained to Kadmon's management that the company needed to report the negative tesevatinib findings to the FDA and shareholders because failure to make such disclosures would result in a material misrepresentation and omission under 15 U.S.C. § 78j and 17 C.F.R. § 240.10b-5 ("Rule 10b-5").⁸ Am. Compl. ¶ 158. The defendants challenge this position by arguing that the plaintiff did not identify conduct he believed to be illegal, the plaintiff did not object to conduct relating to a federal securities law, and the plaintiff did not reasonably believe that the defendants violated a securities law.

To plead his retaliation claim successfully, the plaintiff must allege sufficient factors to show that he reasonably believed that the defendants' conduct violated or would in the future violate an enumerated securities law in SOX. However, the plaintiff has not alleged plausibly that he believed the defendants were at risk of violating the securities laws. In his emails to Kadmon's management, the plaintiff stated that results from the tesevatinib study could wait for the "inclusion . . . at the next scheduled update." Kennedy Decl. Exs. B, C. The lack of urgency in the plaintiff's emails undermines any

⁸ 15 U.S.C. § 78j is enforced through 17 C.F.R. § 240.10b-5. In re PetroChina Co. Ltd. Sec. Lit., 120 F. Supp. 3d 340, 355 (S.D.N.Y. 2015).

allegation that the plaintiff believed a securities violation was imminent.

And in any event, the plaintiff failed to plead adequately that he complained of a future violation of a securities law enumerated in SOX. The plaintiff alleged that the company was "not able to replicate the previous animal testing results" and that "the test results represented new risk information that required disclosure in the annual update to the Investigator's Brochure." Am. Compl. ¶¶ 95, 99. In an attempt to link these allegations to an enumerated securities violation in SOX, the plaintiff alleges that current or potential Kadmon investors would see this information in any update to the IB.

However, the plaintiff does not allege that this information would be material to investors under Rule 10b-5, or that he held a subjective belief and an objectively reasonable belief that this information would be material. See Leshinsky, 942 F. Supp. 2d at 444. The plaintiff alleges generally that shareholders likely would want to know about the tesevatinib animal results and therefore not telling them would be a material omission or misrepresentation. An alleged misrepresentation or omission is material if "there is a substantial likelihood that a reasonable person would consider it important in deciding whether to buy or sell shares of stock." Singh v. Cigna Corp., 918 F.3d 57, 63 (2d Cir. 2019)

(citing Operating Local 649 Annuity Tr. Fund v. Smith Barney Fund Mgmt. LLC, 595 F.3d 86, 92-93 (2d Cir. 2010)) (quotation marks omitted). The statement at issue, or the failure to disclose the statement at issue, must "significantly alter[] the 'total mix' of information made available." Id. (quoting Basic Inc. v. Levinson, 485 U.S. 224, 231-32 (1988)).

In this case, the plaintiff does not allege how a disclosure of the animal study results would impact shareholder decision making or how the study results would change the mix of information made available to shareholders. Indeed, the plaintiff saw no need to update disclosures until the next scheduled update. Accordingly, he has not explained how it would be reasonable to believe that the failure to disclose the tesevatinib study results until some time in the future violated the securities laws. Because the plaintiff has not alleged plausibly that he believed that the defendants had violated the securities laws, or were about to violate the securities laws, the plaintiff has not pleaded a prima facie case of whistleblower retaliation under SOX § 806. See Leshinsky, 942 F. Supp. 2d at 444 ("To demonstrate that a plaintiff engaged in a protected activity, a plaintiff must show that he had both a subjective belief and an objectively reasonable belief that the conduct he complained of constituted a violation of relevant law." (quotation marks omitted)).

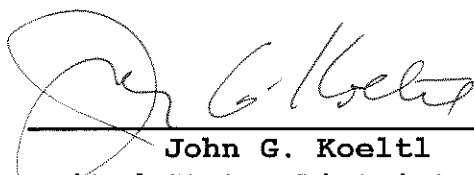
In sum, the plaintiff has failed to plead sufficient facts to show that failure to report the findings of the tesevatinib trial results constituted material misrepresentations or omissions in violation of a relevant securities law. The defendants' motion as it pertains to the plaintiff's SOX claim is **granted**.

CONCLUSION

The Court has considered all of the arguments raised by the parties. To the extent not specifically addressed, the arguments are either moot or without merit. For the reasons explained above, the defendants' motion to dismiss is **granted in part and denied in part**. The Clerk is directed to close **Docket Number 20**.

SO ORDERED.

Dated: New York, New York
September 18, 2019



John G. Koeltl
United States District Judge